UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/821,335	04/09/2004	Paul D. Wightman	58562US005	9992	
*	7590 12/28/200 VE PROPERTIES CO	EXAMINER			
PO BOX 33427		DESAI, RITA J			
ST. PAUL, MN	33133-3427	ART UNIT	PAPER NUMBER		
		1625			
,		·			
SHORTENED STATUTORY	PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MON	NTHS	12/28/2006	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary		Application	No.	Applicant(s)				
		10/821,335		WIGHTMAN ET AL.				
		Examiner		Art Unit				
		Rita J. Desa	i	1625				
The MAILING I Period for Reply	DATE of this communication ap	ppears on the c	over sheet with the c	orrespondence ad	ldress			
WHICHEVER IS LON - Extensions of time may be after SIX (6) MONTHS from - If NO period for reply is spe - Failure to reply within the so Any reply received by the C	TUTORY PERIOD FOR REP IGER, FROM THE MAILING I available under the provisions of 37 CFR 1 the mailing date of this communication. cified above, the maximum statutory period et or extended period for reply will, by statu office later than three months after the mailinent. See 37 CFR 1.704(b).	DATE OF THIS 1.136(a). In no event, d will apply and will e ute, cause the applica	COMMUNICATION, however, may a reply be time xpire SIX (6) MONTHS from tion to become ABANDONE	N. nely filed the mailing date of this of D (35 U.S.C. § 133).				
Status								
1) Responsive to	communication(s) filed on 13	October 2006			• .			
2a) ☐ This action is F	·	is action is nor	ı-final					
'=	•			secution as to the	e merits is			
•	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims			,					
<u> </u>	aloro pondina in the applicatio	ın.						
	Claim(s) 1-51 is/are pending in the application.							
	4a) Of the above claim(s) 10 and 15-51 is/are withdrawn from consideration.							
· · · · ·	5) Claim(s) is/are allowed. 6) Claim(s) <u>1-9 and 11-14</u> is/are rejected.							
	is/are objected to.							
· <u> </u>	•	or alastian rag	uiromont					
	are subject to restriction and/	ror election req	ullement.					
Application Papers								
9) The specificatio	n is objected to by the Examin	ner.			· .			
10) ☐ The drawing(s)	filed on is/are: a)□ ac	cepted or b)	objected to by the F	Examiner.				
Applicant may no	ot request that any objection to the	e drawing(s) be	held in abeyance. See	37 CFR 1.85(a).				
Replacement dra	wing sheet(s) including the corre	ction is required	if the drawing(s) is obj	ected to. See 37 C	FR 1.121(d).			
11)☐ The oath or dec	laration is objected to by the E	Examiner. Note	the attached Office	Action or form P	ΓΟ-152.			
Priority under 35 U.S.C.	§ 119							
12) Acknowledgmer	nt is made of a claim for foreig	n priority unde	r 35 U.S.C. § 119(a)	-(d) or (f).				
	me * c) None of:	,			•			
1. Certified								
2. Certified								
	_							
-	application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.								
Attachmout(-)								
Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)								
	Patent Drawing Review (PTO-948)	4,	4) Interview Summary (PTO-413) Paper No(s)/Mail Date					
3) Information Disclosure S	tatement(s) (PTO/SB/08)		5) D Notice of Informal Patent Application					
Paper No(s)/Mail Date 6) Other:								

DETAILED ACTION

Applicants had elected group I claims 1-9 and 11-14.

Applicants have not amended the claims to the elected group.

The rejection of claims 1-9, 11-14 under 35 USC 102(b) over US 4,689,338 Gerster et al still stands.

The examiner is repeating the rejection here.

The claims 1-9 and 11-14 still stand rejected under 35 USC 102(b).

Applicants arguments are not fully convincing. The prior art does disclose the polyethelene macro-molecules formulation. These could be bonded to the reactive groups on the IRM molecules. Could be H bonding too.

Applicants specifications on page 21, lines 19-21 clearly states that the IRM compound can be blended or mixed in. See below.

IRM can be released and function in that manner. That is, for example, the IRM can be simply dissolved or blended into a macromolecular support material (e.g., as in a polymeric coating). Mixtures of the two types can also be used where desirable.

Applicants in their specification have not shown how the bonding takes place on the support. It just states it could be covalently bonded.

Hence the rejection still stands.

Applicants arguments are not persuasive. Applicants argue that theirs has a covalent bond, but he specification teacher that it just needs to be a strong bond.

.

Art Unit: 1625

The reference teaches the polyethylene glycol same as that given in applicants description of a macromolecular support material.

Also applicants specifications clearly teaches that the compound is attached by a sufficiently strong bond (H bonding is sufficiently strong) which may sometimes be covalently bonded.

During "formulation" drugs can get attached to the carrier via bonding.

Also see page 27 of the specification which clearly teaches that it can be just a hydrogen bonding

which reads on formulation.

" Attachment to Substrates:

IRMs can be attached to a macromolecular support material through either covalent attachment or non-covalent attachment. Non-covalent attachment of an IRM to a macromolecular support material includes attachment by ionic interaction or hydrogen bonding, for example."

In view of the lack of the scope of enablement the above rejection still stands.

Applicants claims are drawn to a support complex not a method of using it.

The rejection of claims 1-9 and 11 under 35 U.S.C. 112 first paragraph scope of enablement still stands. Again applicants claims are drawn to a complex itself, not to a method of using them. Thus the complex as such should be clearly enabled.

Claim 3 is drawn to a gel, foam, fiber, a hydrogel, a bead.

Thus it is clear that the compound is not dissolved or blended.

Art Unit: 1625

It is unclear how it can be covalently bonded. The location of the site of the covalent bond on a bead will be different than that on a gel.

Regarding applicants arguments regarding:-

Breadth of the claims: Applicants arguments that they cover a broad variety of known substrates may be correct, however applicants have not show the active sites of where the reaction takes place and where the covalent bonding occurs, if covalent bonding is what applicants claims. Applicants description of the support material is

"Typically, the macromolecular support material is in the form of a solid (i.e., a solid support such as particles, fibers, membranes, films), but can also be in the form of a polymeric gel, sponge, or foam, for example. A macromolecular support material can be made of a variety of materials, including substrates made of ceramic, glassy, metallic, or polymeric materials, or combinations of materials. The terms "substrate," "support material," or "support," may also be used herein to refer to a macromolecular support material. "

Glassy and ceramic compounds are not known to easily for a covalent bond with compounds. The nature of the invention: applicants have not supported the fact that supports, generally to form complexes are known. Applicants support materials include compounds that do not form a covalent bond by itself. Thus with little known, applicants need to provide more as to how and where are the covalent bonds formed between the compound and the substrate to form a "complex".

State of the art:- Applicants agree that the state of the art does not teach the complexes.

Art Unit: 1625

Level of predictability; even though the level of skill in the art is high, there is no predictability that compounds would form complexes with glass. Applicants have not shown how these complexes are formed. Again applicants specification clearly states it can be ionic or a Hydrogen bonding. Does not have to be covalently bonded.

If it is so, as required by claim 2, applicants have not enabled where the site and location and between the compound and the substrate is.

Thus applicants have not provided proper direction as to the formation and enablement of the complex.

There is an undue amount of experimentation to make the invention of the applicants.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that,

based on the evidence regarding each of the above factors, the specification, at the

time the application was flied, would not have taught one skilled in the art how to

make and/or use the full scope of the claimed invention without undue

experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed.

Cir. 1993)." That conclusion is clearly justified here. Thus, undue

experimentation will be required to practice Applicants' invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1625

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

> Rita J. Desai Primary Examiner Art Unit 1625

KNesar 12/22/06

Application/Control Number: 10/821,335 Page 7

Art Unit: 1625

December 22, 2006